

Rhode Island Department of Health Institutional Review Board

Minutes of Meeting February 3, 2005

In attendance: Utpala Bandy, Jay Buechner, John Fulton, Leonard Green (Vice-Chair), Ewa King (for Bruce McIntyre), Joann Lindenmayer (Chair), Sharon Marable (for Leonard Green from 10:10 to adjournment), Elizabeth Shelov, Vivian Weisman

Absent but excused: Bruce McIntyre

The Chair began the meeting at 9:30 a.m.

1) Continuation IRB Review: HEALTH IRB #2002-14: Spoken work recognition in early language acquisition: James L. Morgan, Ph.D., Department of Cognitive and Linguistic Sciences, Brown University

The Chair gave a brief history of this project. Dr. Morgan's project is funded by NIH and was begun in 1991. In 1998 Dr. Morgan requested that Vital Statistics provide him with names, addresses and phone numbers of families in which a birth has occurred and he has used this information to recruit families with infant/toddlers as participants in cognitive and linguistic studies. The proposal was reviewed and approved at a full meeting of the HEALTH IRB in 1998, and Dr. Morgan has submitted continuation review applications since that time and the HEALTH IRB has approved all. Dr. Morgan submitted the most recent continuation application in August 2004. The proposal was reviewed at the January 6, 2005 meeting of the HEALTH IRB, and the Board recommended that approval be extended for three months pending receipt of a full proposal with some modifications (detailed in Dr. Lindenmayer's letter to him of November 17, 2004). This review was based on that full proposal and his responses to the requested modifications. Discussion of this proposal centered on two issues. The Board expressed concern that the telephone script used to recruit subjects for this study conveyed the impression that investigators were calling RI households at random when this was not the case. A related concern was that a "cold" call to a household in the database might occur under circumstances that could compromise a respondent's ability to make an informed and voluntary decision about whether or not to participate in this study with his/her child. The Board discussed replacing the present postcard with a letter, thereby addressing both issues of full disclosure and protection of potential participants.

Motion by Ms. Shelov and seconded by Ms. Weisman: The Board extend Dr. Morgan's approval for another three months since doing so would not increase the present minimal risk to human subjects of this research, and Dr. Morgan replace the postcard presently used in this project with a letter that invites a family to participate and that includes the following information: 1) the investigator has received approval from the HEALTH IRB for the study, and 2) the Health Department released contact information for the respondent. The letter could subsequently alert the family to a follow-up phone call. On a voice vote, the Board voted on the motion as follows: **Approve: 8; Not approve: 0; Abstain: 0.** Dr. Lindenmayer will communicate this information to Dr. Morgan and will inform him that a full board review will be conducted again within the next three months but no later than the May meeting of the IRB.

2) Release of information from the Health Department: Noting that informed consent is integral to every IRB application, and that investigators were required to obtain informed consent from potential research participants or justify requesting a waiver of informed consent, the Chair asked whether similar considerations should apply to investigators who request identifying information from the Health Department. Board members noted that

information held by the Health Department might be attended by various degrees of protection. For example, the occurrence, or fact, of a birth may or may not be protected from release. Under certain Acts the State of Rhode Island permits release of information for specific purposes as, for example, from the RI Cancer Registry. Furthermore, certain information may be protected under Rhode Island law but not under IRB (federal) regulations, and in such cases, state law preempts federal regulations. Lastly, the benefit or releasing such information must be carefully weighed against the risks to individuals of releasing it. The release of identifying information held by certain programs, for example, HIV/AIDS, might subject individuals to risks so great (economic, social, political) that any benefits of releasing it would not outweigh the potential risks of releasing it. The Board will take a closer look at Rhode Island law that is relevant to this issue and the Chair will ask Bruce McIntyre for assistance with this. However, consensus it that it is up to the IRB, before approving any such release of information, to ensure that its release does not contradict any federal, state, or programmatic context. If, after such consideration it is found that such information may be released, it is up to the IRB to weigh benefits and risks to release of information. It is not up to the investigators to address informed consent when requesting information from the Health Department.

- 3) **Expedited Review:** The Chair informed the Board that she had reviewed the following proposals in an expedited manner and approved them on the following dates:
 - a) HEALTH IRB #2004-06: Review of the Title X Family Planning Program Evaluation Activities and Assessment of Current Evaluation Needs; Cynthia Fowler, Ph.D., Research Triangle International and Lori Zelano, Division of Family Health; [January 20, 2005]
 - b) HEALTH IRB #2004-09: Mapping of Tick-transmitted Disease in Rhode Island; Sarah Rodgers, Ph.D. and Thomas Mather, Ph.D., Center for Vector-Borne Disease, University of Rhode Island [February 3, 2005]
- 4) **Annual reviews:** Board members will meet within the next few weeks to review older IRB files to determine which projects require updated information, e.g., annual reviews or IRB notification by the Principal Investigator of project termination. Board members will design forms to meet these purposes.
- 5) **Update on administrative resources:** The Chair and Vice-Chair met with the Department's Executive Committee on January 25, 2005 to discuss administrative resources for the HEALTH IRB. The Committee agreed that it was important that the Health Department not cede the responsibility of IRB review to another Board, and the Committee expressed its support for identifying administrative resources for the Board, but no additional actions were taken at this meeting. A suggestion was made that the Chair prepare a transition paper on the IRB for the Director-nominee (Dr. Dave Gifford) and that he be invited to the March meeting of the IRB.
- 6) **Update on new members:** The Chair informed the Board that Rob Jones, Chair of the Minority Health Advisory Committee, has accepted an appointment to serve as a full member of the IRB
- 7) **New business:** none

Motion to adjourn by Sharon Marable, seconded by John Fulton. On a voice vote, the Board voted on the motion as follows: **Approve: 8; Not approve: 0; Abstain: 0.** The meeting was adjourned at 11:20 a.m.

Next meeting: March 3, 2005 (Beck Conference Room)